



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HEIDER *et al.*

Appl. No. 10/052,641

Filed: January 23, 2002

For: **Method for Diagnosis and
Therapy of Hodgkin's
Lymphomas**

Confirmation No. 3959

Art Unit: 1642

Examiner: *To be assigned*

Atty. Docket: 0652.1910001/EKS/PSC

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicant's undersigned representative submits the following concise explanation of the relevance of the non-English language documents. Document Nos. AO1, AP1 and AL2, cited on form PTO 1449:

Document **AL1**, European Patent Publication No. 0 531 300 B1 is in the German language. Document **AL1** relates to variant CD44-surface proteins and cDNA sequences and antibodies for proteins for use in diagnosis and therapy for tumor metastases. An English language abstract of this document is provided as Document **AR16**;

Document **AM1**, European Patent Publication No. 0 538 754 A2 is in the German language. Document **AM1** relates to the use of variant CD44 mammalian cell surface protein antibodies to prepare compositions suppressing the immune response in mammals. An English language abstract of this document is provided as Document **AS16**;

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Document **API**, PCT Patent Publication No. WO 95/00851 is in the German Language. Document **API** relates to antibodies and nucleic acids encoding the epitopes used in the diagnosis and/or analysis of tumors by detecting at least one variable exon of the CD44 gene or corresponding epitope. An English language abstract of this document is provided as Document **AT16**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120, 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed more than three months after the U.S. filing date, but before the first mailing of an Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: 8/14/02

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
0652.1910001/EKS/PSCAPPLICATION NO.
10/052,641APPLICANT
HEIDER et al.FILING DATE
January 23, 2002GROUP
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	EP 0 531 300 B1	03/17/1993	Europe			Yes No
	AM1	EP 0 538 754 A2	04/28/1993	Europe			Yes No
	AN1	WD 94/02633 A1	02/03/1994	WIPO			Yes No
	AO1	WD 94/12631 A1	06/09/1994	WIPO			Yes No
	AP1	WD 95/00851 A1	01/05/1995	WIPO			Yes No

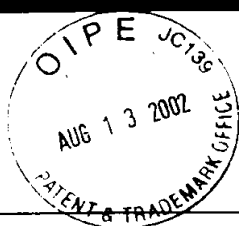
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AE	1	Breitz, H.B., et al., "Clinical Experience with Rhenium-186-Labeled Monoclonal Antibodies for Radioimmunotherapy: Results of Phase I Trials," J. Nucl. Med. 33:1099-1109, The Society of Nuclear Medicine (1992)
	AS	1	Breitz, H.B., et al., "Pharmacokinetics and Normal Organ Dosimetry Following Intraperitoneal Rhenium-186-Labeled Monoclonal Antibody," J. Nucl. Med. 36:754-761, The Society of Nuclear Medicine (May 1995)
	AT	1	Chatterjee, M.B. et al., "Idiotypic antibody immunotherapy of cancer," Cancer Immunol. Immunother. 38:75-82, Springer-Verlag (1994)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AI,2	WO 95/00658 A1	01/05/1995	WIPO			Yes XNo
	AK						Yes No
	AL						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Chaudhary V.K. et al., "A rapid method of cloning functional variable-region antibody genes in Escherichia coli as single-chain immunotoxins," <i>Proc. Natl. Acad. Sci. USA</i> 87:1066-1070, National Academy Press (1990)
	AS	2	Ermak, G., et al., "Restricted Patterns of CD44 Variant Exon Expression in Human Papillary Thyroid Carcinoma," <i>Cancer Res.</i> 56:1037-1042, American Association for Cancer Research (March 1996)
	AT	2	Fox, S.B., et al., "CD44 and cancer screening," <i>Lancet</i> 342:548-549, Williams & Wilkens (1993)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AF	<u>3</u>	Fox, S.B., et al., "Normal Human Tissues, in Addition to Some Tumors, Express Multiple Different CD44 Isoforms," <i>Cancer Res.</i> 54:4539-4546, American Association for Cancer Research (1994)
	AS	<u>3</u>	Friedrichs, K., et al., "CD44 Isoforms Correlate with Cellular Differentiation but not with Prognosis in Human Breast Cancer," <i>Cancer Res.</i> 55:5424-5435, American Association for Cancer Research (November 1995)
	AT	<u>3</u>	Fujiwara, K., et al., "Expression of a Lymphocyte Adhesion Molecule (CD44) in Malignant Lymphomas: Relevance to Primary Site, Histological Subtype and Clinical Stage," <i>Acta Med. Okayama</i> 47:215-222, Okayama University Medical School (1993)

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	AO						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AF	<u>4</u>	Ghaffari, S., et al., "Differentiation-Associated Changes in CD44 Isoform Expression During Normal Hematopoiesis and Their Alteration in Chronic Myeloid Leukemia," <i>Blood</i> 86:2976-2985, W.B. Saunders Company (October 1995)
	AS	<u>4</u>	Ginthert, U., et al., "A New Variant of Glycoprotein CD44 Confers Metastatic Potential to Rat Carcinoma Cells," <i>Cell</i> 65:13-24, Cell Press (1991)
	AT	<u>4</u>	Gura, T., "Systems for Identifying New Drugs Are Often Faulty," <i>Science</i> 278:1041-1042, American Association for the Advancement of Science (November 1997)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AP	<u>5</u>	Heider, K.-H., et al., "A Human Homologue of the Rat Metastasis-associated Variant of CD44 Is Expressed in Colorectal Carcinomas and Adenomatous Polyps," <i>J. Cell Biol.</i> 120:227-233, The Rockefeller University Press (1993)
	AS	<u>5</u>	Heider, K.-H., et al., "Expression of CD44 isoforms in human renal cell carcinomas," <i>Virchows Arch.</i> 428:267-273, Springer-Verlag (July 1996)
	AT	<u>5</u>	Hofmann, M., et al., "CD44 Splice Variants Confer Metastatic Behavior in Rats: Homologous Sequences Are Expressed in Human Tumor Cell Lines," <i>Cancer Res.</i> 51:5292-5297, American Association for Cancer Research (1991)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
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	AP						Yes No

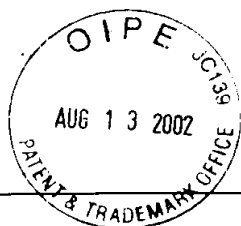
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Horst, E., et al., "Expression of a Human Homing Receptor (CD44) in Lymphoid Malignancies and Related Stages of Lymphoid Development," <i>Leukemia</i> 4:383-389, Williams & Wilkins (1990)
	AS	<u>6</u>	Horst, E., et al., "Adhesion Molecules in the Prognosis of Diffuse Large-Cell Lymphoma: Expression of a Lymphocyte Homing Receptor (CD44), LFA-1 (CD11a), ICAM-1 (CD54)," <i>Leukemia</i> 4:595-599, Williams & Wilkins (1990)
	AT	<u>6</u>	Jackson, D.G., et al., "Multiple Variants of the Human Lymphocyte Homing Receptor CD44 Generated by Insertions at a Single Site in the Extracellular Domain," <i>J. Biol. Chem.</i> 267:4732-4739, The American Society for Biochemistry and Molecular Biology, Inc. (1992)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AE	<u>7</u>	Jain, R.K., "Barriers to Drug Delivery in Solid Tumors," <i>Sci. Am.</i> 271:58-65, Scientific American, Inc. (1994)
	AS	<u>7</u>	Jalkanen, S., et al., "Lymphocyte Homing and Clinical Behavior of Non-Hodgkin's Lymphoma," <i>J. Clin. Invest.</i> 87:1835-1840, The American Society for Clinical Investigation, Inc. (1991)
	AT	<u>7</u>	Juweid, M., et al., "Treatment of Non-Hodgkin's Lymphoma with Radiolabeled Murine, Chimeric, or Humanized LL2, an Anti-CD22 Monoclonal Antibody," <i>Cancer Res. (Suppl.)</i> 55:5899s-5907s, American Association for Cancer Research (December 1995)

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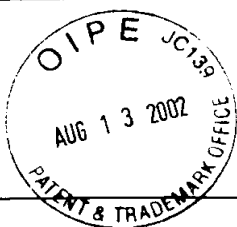
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	AF	E	Kaufmann, M., et al., "CD44 variant exon epitopes in primary breast cancer and length of survival," <i>Lancet</i> 345:615-619, The Lancet, Ltd. (March 1995)
	AS	E	Koopman, G., et al., "Activated Human Lymphocytes and Aggressive Non-Hodgkin's Lymphomas Express a Homologue of the Rat Metastasis-associated Variant of CD44," <i>J. Exp. Med.</i> 177:897-904, The Rockefeller University Press (1993)
	AT	E	Mackay, C.R. et al., "Expression and Modulation of CD44 Variant Isoforms in Humans," <i>J. Cell. Biol.</i> 124:71-82, The Rockefeller University Press (1994)

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U.S. PATENT DOCUMENTS

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	AA						Yes No
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	AA						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AA	9	Möller, P., et al., "Venular endothelium binding molecules CD44 and LECA-1 in normal and malignant B-cell populations. A comparative study," <i>Virchows Arch. A. Pathol. Anat.</i> 421:305-313, Springer-Verlag (1992)
	AA	9	Mulder, J.-W.R., et al., "Colorectal cancer prognosis and expression of α -v6-containing CD44 proteins," <i>Lancet</i> 344:1470-1472, The Lancet, Ltd. (1994)
	AA	9	Pals, S.T., et al., "Expression of Lymphocyte Homing Receptor as a Mechanism of Dissemination in Non-Hodgkin's Lymphoma," <i>Blood</i> 73:885-888, Grune & Stratton (1989)

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	AP						Yes No

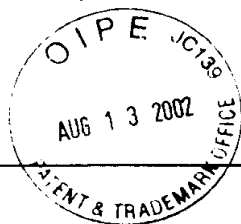
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	AF	<u>10</u>	Picker, L.J., et al., "Expression of Lymphocyte Homing Receptor Antigen in Non-Hodgkin's Lymphoma," <i>Am. J. Pathol.</i> 130:496-504, American Association of Pathologists (1988)
	AS	<u>10</u>	Press, O. W., et al., "Phase II trial of "I-B1 (anti-CD20) antibody therapy with autologous stem cell transplantation for relapsed B cell lymphomas," <i>Lancet</i> 346:336-340, The Lancet, Ltd. (August 1995)
	AT	<u>10</u>	Quadri, S.M., et al., "Evaluation of Indium-111- and Yttrium-90-Labeled Linker-Immunocjugates in Nude Mice and Dogs," <i>J. Nucl. Med.</i> 34:938-945, The Society of Nuclear Medicine, Inc. (1993)

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	AM						Yes No
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>11</u>	Eistamäki, R., et al., "Serum CD44 in Malignant Lymphoma: An Association With Treatment Response," <i>Blood</i> 84:238-243, W.B. Saunders Company (1994)
	AS	<u>11</u>	Eistamäki, R., et al., "CD44v6 Expression in Non-Hodgkin's Lymphoma: an Association with Low Histological Grade and Poor Prognosis," <i>J. Pathol.</i> 176:259-267, John Wiley & Sons, Ltd. (July 1995)
	AT	<u>11</u>	Salles, G., et al., "Alternatively Spliced CD44 Transcripts in Diffuse Large-Cell Lymphomas: Characterization and Comparison With Normal Activated B Cells and Epithelial Malignancies," <i>Blood</i> 82:3539-3547, W.B. Saunders Company (1993)

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	AP						Yes No

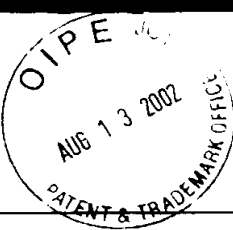
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	AP	<u>12</u>	Savage, P., et al., "A recombinant single chain antibody interleukin-2 fusion protein," Br. J. Cancer 67:304-310, Macmillan Press, Ltd. (1993)
	AS	<u>12</u>	Screaton, G.R., et al., "Genomic structure of DNA encoding the lymphocyte homing receptor CD44 reveals at least 12 alternatively spliced exons," Proc. Natl. Acad. Sci. USA 89:12160-12164, National Academy Press (1992)
	AT	<u>12</u>	Screaton, G.R., et al., "The Identification of a New Alternative Exon with Highly Restricted Tissue Expression in Transcripts Encoding the Mouse Pgp-1 (CD44) Homing Receptor," J. Biol. Chem. 268:12235-12238, The American Society for Biochemistry and Molecular Biology, Inc. (1993)

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0652.1910001/EKS/PSC	APPLICATION NO. 10/052,641
	APPLICANT HEIDER et al.	
	FILING DATE January 23, 2002	GROUP 1642

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
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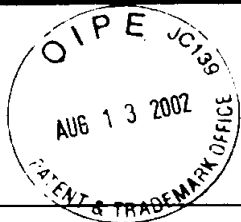
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AF	<u>18</u>	Seaver, S., "Monoclonal Antibodies in Industry: More Difficult Than Originally Thought," <i>Genet. Eng. News</i> 14:10,21, Mary Ann Liebert, Inc. (1994)
	AS	<u>19</u>	Seiter, S., et al., "Prevention of Tumor Metastasis Formation by Anti-Variant CD44," <i>J. Exp. Med.</i> 177:443-455, The Rockefeller University Press (1993)
	AT	<u>19</u>	Stamenkovic, I., et al., "A Lymphocyte Molecule Implicated in Lymph Node Homing Is a Member of the Cartilage Link Protein Family," <i>Cell</i> 56:1057-1062, Cell Press (1989)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
0652.1910001/EKS/PSCAPPLICATION NO.
10/052,641APPLICANT
HEIDER et al.FILING DATE
January 23, 2002GROUP
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
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	AO						Yes No
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	AR	<u>14</u>	Stauder, R., et al., "CD44 Variant Isoforms in Non-Hodgkin's Lymphoma: A New Independent Prognostic Factor," <i>Blood</i> 85:2885-2899, W.B. Saunders Company (May 1995)
	AS	<u>14</u>	Tanabe, K.K., et al., "Expression of CD44R1 adhesion molecule in colon carcinomas and metastases," <i>Lancet</i> 341:725-726, Williams & Wilkins (1993)
	AT	<u>14</u>	Terpe, H.-J., et al., "CD44 variant isoforms are preferentially expressed in basal epithelial of non-malignant human fetal and adult tissues," <i>Histochemistry</i> 101:79-89, Springer-Verlag (1994)

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	AL2						Yes XNo
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	<u>15</u>	Thomas, G.D., et al., "Antibodies for tumour immunodetecting and methods for antibody radiolabelling," in <i>Antibodies. Volume II. A Practical Approach</i> , Volume II, Catty, D., ed., IRL Press, Oxford, UK, pp. 223-244 (1989)
	AS	<u>15</u>	Tölg, C., et al., "Splicing choice from ten variant exons establishes CD44 variability," <i>Nucl. Acids Res.</i> 21:1225-1229, Oxford University Press (1993)
	AT	<u>15</u>	Vriesendorp, H.M. et al., "Review of Five Consecutive Studies of Radiolabeled Immunoglobulin Therapy in Hodgkin's Disease," <i>Cancer Res. (Suppl.)</i> 55:5888s-5892s, American Association for Cancer Research (December 1995)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>16</u>	Dialog File 351, Accession No. 91-340908/199147, Derwent WPI English language abstract for EP 0 531 300 B1 (Document AL1)
	AS	<u>15</u>	Dialog File 351, Accession No. 93-136002/199317, Derwent WPI English language abstract for EP 0 538 754 A2 (Document AM1)
	AT	<u>16</u>	Dialog File 351, Accession No. 95-052230/199507, Derwent WPI English language abstract for WO 95/00851 (Document AP1)

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